AMENDED IN ASSEMBLY JULY 16, 2007

AMENDED IN ASSEMBLY JUNE 27, 2007

AMENDED IN SENATE JUNE 4, 2007

AMENDED IN SENATE MAY 15, 2007

SENATE BILL No. 606

Introduced by Senator Scott
(Coauthor: Senator Kuehl)
(Coauthors: Assembly Members Brownley and Ruskin)

February 22, 2007

An act to add Division 112.6 (commencing with Section 130650) to the Health and Safety Code, relating to pharmaceutical information.

LEGISLATIVE COUNSEL'S DIGEST

SB 606, as amended, Scott. Pharmaceutical information: clinical trial data.

Existing law, the Sherman Food, Drug, and Cosmetic Law, regulates the packaging, labeling, and advertising of food, drugs, and cosmetics, under the administration of the State Department of Public Health.

This bill would require a pharmaceutical ~~company~~ *manufacturer* that sells, delivers, offers for sale, or gives away pharmaceutical drugs within the state to make publicly available the results of every completed clinical trial, except a phase I trial or ~~bioequivalence study~~ *study used to establish bioequivalence*, for that drug and an explanation of noncompletion for any clinical trial, except a phase I trial, that the ~~company~~ *manufacturer* initiates or sponsors the initiation of, but does not complete.

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Division 112.6 (commencing with Section 130650) is added to the Health and Safety Code, to read:

DIVISION 112.6. PHARMACEUTICAL DRUG INFORMATION AND SAFETY ACT

130650. This division shall be known, and may be cited as the "Pharmaceutical Drug Information and Safety Act."

130651. For purposes of this division, the following definitions shall apply:

(a) "Clinical trial" means a hypothesis testing clinical investigation that involves any experiment to test a specific clinical hypothesis as well as the safety or efficacy of a drug or biological product with one or more human subjects.

(b) (1) "Pharmaceutical manufacturer" means any entity that is engaged in ~~either~~ *any* of the following:

(A) The production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis.

(B) The packaging, repackaging, labeling, relabeling, or distribution of prescription drug products.

(2) "Pharmaceutical manufacturer" does not include ~~a~~ *any of the following:*

(A) A corporation that meets the definition in paragraph (1) solely because it is in the business of repackaging or compounding prescriptions, if that corporation is not in the business of developing FDA-approved drug products for sale to the general public.

(B) A wholesale distributor of drugs, mail order pharmacy, or retail pharmacy licensed under state law.

(c) "Pharmaceutical drug" means any drug which is approved by the federal Food and Drug Administration and commercially available in the state.

(d) "Phase I trial" means the initial studies designed exclusively to determine the metabolic and pharmacologic actions of drugs in humans, and the side effects associated with increasing doses, and to gain early evidence of effectiveness.

~~(e) "Serious adverse events" means any untoward medical occurrence, in a patient or clinical investigation subject who has been administered a pharmaceutical product, which does not necessarily have to have a causal relationship with this treatment.~~

(e) (1) "Serious adverse events" means any adverse drug experience occurring at any dose that results in any of the following outcomes:

(A) Death.

(B) A life-threatening adverse drug experience.

(C) Inpatient hospitalization or prolongation of existing hospitalization.

(D) A persistent or significant disability or incapacity.

(E) A congenital anomaly or birth defect.

(2) "Serious adverse events," as used in this subdivision, may include important medical events that may not result in death, be life-threatening, or require hospitalization when, based upon appropriate medical judgment, these events may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in paragraph (1).

(f) "Scientific work product" means a writing that reflects a scientist, clinician, or researcher's impressions, conclusions, opinions, research, statistical calculations, or theories.

(g) "Sponsor" means an individual or pharmaceutical manufacturer, governmental agency, academic institution, private organization, or other organization that takes responsibility for or initiates a clinical investigation.

130652. Any pharmaceutical ~~company~~ *manufacturer* that sells, delivers, offers for sale, or gives away any pharmaceutical drug within this state shall make publicly available, in accordance with Section 130654, the results of every completed clinical trial, except for a phase I trial or ~~bioequivalence study~~ *study used to establish bioequivalence*, that the ~~company~~ *manufacturer* conducts or sponsors on and after October 15, 2002, for every pharmaceutical drug that the ~~company~~ *manufacturer* sells, delivers, offers for sale, or gives away in this state. The information required to be provided with the results shall include, but not be limited to, all of the following:

(a) The name of the trial.

(b) Commercial and chemical name of all pharmaceutical drugs tested, including comparator drugs, if any.

(c) Initiation and completion dates of the trial.

(d) Purposes of the trial, including the medical condition or conditions studied.

(e) Outcomes of the trial including any time points at which outcome data were measured and used either subsequently for marketing purposes or other actions taken to publicly promote the outcomes of a trial, including, but not limited to, a news release.

(f) Trial funding sources.

(g) Number of patients initially enrolled in the trial.

(h) Number of patients completing the trial.

(i) A list of all specific characteristics used to include and exclude people as trial participants, such as gender, race, age, preexisting health conditions, and an explanation of the suitability of the trial participant population for the purposes of the study.

(j) Names and contact information for principal sponsors of the trial. Contact information shall include at least a telephone number and mailing address for public inquiry.

(k) Names and contact information for principal researchers of the trial.

(*l*) Frequency, severity, and nature of all serious adverse events experienced by trial participants, including participants that did not complete the trial, for each drug.

(m) If the study involved a comparison of two or more pharmaceutical drugs, all information regarding the relative efficacy of each drug and the relative frequency, severity, and nature of all serious adverse events experienced by trial participants, including participants that did not complete the trial.

(n) If any of the data from the study were published by a clinical trial investigator in a peer-reviewed medical journal that summarizes the safety or efficacy results of the clinical trial, a complete citation and, if available, a hyperlink for each of these publications.

(o) A hyperlink to the package insert approved by the federal Food and Drug Administration for the drug.

130653. Any pharmaceutical ~~company~~ *manufacturer* that sells, delivers, offers for sale, or gives away any pharmaceutical drug within this state shall make publicly available, in accordance with Section 130654, an explanation of noncompletion for any clinical trial, except a phase I trial, that the pharmaceutical ~~company~~ *manufacturer* initiates, or sponsors the initiation of, on and after

October 15, 2002, but does not complete for every pharmaceutical drug that the ~~company~~ *manufacturer* sells, delivers, offers for sale, or gives away in this state. The explanation shall state why the clinical trial was terminated and shall include all available information described in Section 130652.

130654. (a) The information required pursuant to Sections 130652 and 130653 shall be submitted for inclusion on the Web site administered by the National Institutes of Health or on another publicly accessible Web site, or shall be posted on a publicly accessible Web site directly linked to the pharmaceutical ~~company's~~ *manufacturer's* primary corporate Web site. For purposes of this section, a Web site is publicly accessible only if it provides free, nonsubscription access to its contents and clearly indicates the location and instructions for downloading the files or information submitted pursuant to this division.

(b) If a drug is sold, delivered, offered for sale, or given away within the state prior to January 1, 2008, and has a trial completion or termination date on or before January 2008, the pharmaceutical ~~company~~ *manufacturer* shall submit or post the information pursuant to subdivision (a) by January 1, 2009. If a drug is sold, delivered, offered for sale, or given away within the state prior to January 1, 2008, and has a trial completion or termination date after January 2008, the pharmaceutical ~~company~~ *manufacturer* shall submit or post the information pursuant to subdivision (a) within one year of the completion or termination date of the trial.

(c) If a drug is sold, delivered, offered for sale, or given away within the state on or after January 1, 2008, the pharmaceutical ~~company~~ *manufacturer* shall submit or post the information pursuant to subdivision (a) within one year of the date that the drug is first sold, delivered, offered for sale, or given away within the state or within one year of the completion or termination date of the trial, whichever is later.

(d) Notwithstanding subdivisions (b) and (c), a pharmaceutical ~~company~~ *manufacturer* may extend the deadline requirements of these subdivisions by not more than six months if both of the following occur:

(1) The compilation and analysis of the data in the clinical trial have not been substantially completed by the appropriate deadline described in subdivision (b) or (c).

(2) The pharmaceutical ~~company~~ *manufacturer* submits for inclusion on the Web site administered by the National Institutes of Health or on another publicly accessible Web site, or posts on a publicly accessible Web site directly linked to the pharmaceutical ~~company's~~ *manufacturer's* primary corporate Web site, a statement that the availability of the information required by this section has been delayed, a statement that provides the reasons for the delay, and a statement that provides a date when the information is anticipated to be made available.

(e) Notwithstanding subdivisions (b), (c), and (d), a pharmaceutical ~~company~~ *manufacturer* may extend the deadline requirements of these subdivisions if the ~~company~~ *manufacturer* submits the results of the clinical trial in a peer-reviewed journal for publication. However, the extension of these deadline requirements may not extend beyond one year from the applicable deadline described in those subdivisions or 30 days from the date of publication, whichever is earlier.

130655. (a) A pharmaceutical ~~company~~ *manufacturer* subject to the requirements of this division that complies with a federal law or regulation that requires public disclosure on a Web site of information that is substantially similar to the information required pursuant to this division shall be deemed to be in compliance with this division.

(b) No provision of this division shall be construed to require the public disclosure of a trade secret, as defined in Section 3426.1 of the Civil Code, or scientific work product.

(c) If some factors, conclusions, results, or points of data from a clinical trial are deemed a trade secret, as defined in Section 3426.1 of the Civil Code, or scientific work product, only those sections shall be withheld from disclosure.

(d) If parts or all of a clinical trial are withheld from disclosure because this information constitutes a trade secret, as defined in Section 3426.1 of the Civil Code, or scientific work product, a pharmaceutical ~~company~~ *manufacturer* shall disclose the fact that information ~~was~~ *is being* withheld because it constitutes a trade secret *or scientific work product*.

(e) Nothing in this division shall be construed to permit public disclosure of information currently protected from public disclosure under the federal Health Insurance Portability and Accountability Act (HIPAA) (Public Law 104-191).

(f) This division shall apply only to the ~~regulatory~~ sponsors of clinical trials.

~~(g) Nothing in this division shall either hinder or enhance the disclosure of any scientific work product during the discovery period of litigation.~~

130658. Nothing in this division shall constitute a duty by the State Department of Public Health to enforce the implementation of this division.

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